

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 180-187, 190, 191 and 192 will be pending in the application subsequent to entry of this Amendment.

In the current Official Action, claims 188 and 189 are objected to as dependent upon a rejected base claim. With the examiner's comments in the mind the subject matter of these two claims has been written in independent form and now appear in claim 190, which is a combination of claims 180, 186 and 188, and 191 which is a combination of claims 180 and 189.

With these two claims written in independent form, the claims are fully allowable as they no longer depend from a rejected claim.

Applicants note the examiner's comment at the top of page 3 of the Action; "While there is an electrical component to the invention of (the) Canham (citation), such a component is not excluded by the instant claims." While the claims in this application are directed to methods, not articles, a point that is developed further below, independent claim 192 has been added specifying that the implant **consists of** a resorbable mesoporous silicon carrier material having a beneficial substance associated therewith which is implanted, thus making it clear that an "electrical component" is not included.

The balance of the Official Action relates to an alleged anticipation rejection based upon US patent 6,666,214 to Canham, the senior inventor in respect to the present application. This patent was first cited in the current Official Action yet the content of it has been thoroughly considered during the previous examination and, in fact, claim 180 as it presently stands was determined to be patentable over the content of the "newly cited" US patent.

The substance of the rejection in the current Official Action is as follows:

A mesoporous implant having the thickness, porosity and surface area characteristics of the instant invention is disclosed at Abstract, col. 8, lines 10-26. Porosity if [sic] set out in the claims along with drug delivery (see claims 1-3 and 7 in particular). While there is an electrical component to the invention of Canham, such a component is not excluded by the instant claims. The instant claims are anticipated by Canham.

Applicants note that US 6,666,214 – first cited in the current Official Action -- is a national phase entry from WO 97/06101, (WO '101). WO '101 has already been cited in

connection with the prosecution of this patent application and has been discussed at significant length. One must not lose sight of this during the various rounds of prosecution – the content of US 6,666,214 is certainly not a completely new citation.

In short, the Examiner has previously come to the conclusion that the present claims are allowable over WO '101. In the Office Action dated March 27, 2008 the Examiner withdrew his novelty objections in connection with WO '101 and considered claims 180 and 184-89 were allowable.

More specifically, on reviewing the Examiner's comments reproduced above it seems that the Examiner has again not taken into account that the present claims are directed to methods but instead they are being examined as directed to an implant per se.

Claim 180 of the present application is in the following terms:

180. A method of administering a beneficial substance to a human or animal subject, said method comprising subcutaneously implanting an implant comprising a resorbable mesoporous silicon carrier material having a beneficial substance associated therewith, wherein the mesoporous silicon carrier material is resorbable or bioerodible by mammalian subcutaneous physiological fluids.

The following comments are a synopsis of arguments which were successful in the past for overcoming the cited art which it appears the Examiner has forgotten about. They have been adapted to take account that the Examiner is referring to US 6,666,214 rather than the corresponding PCT document.

US 6,666,214 (Canham) does not disclose a method of delivering a beneficial substance to a human or animal subject subcutaneously. By way of background, the subcutaneous layer (sometimes referred to as the subcutis) is the layer of tissue directly underlying the cutis (the two outer layers of skin) and is mainly composed of adipose tissue. Its physiological function includes insulation and storage of nutrients. It is known to administer injections subcutaneously.

In addition, Canham does not disclose a method of delivering a beneficial substance to a human or animal subject subcutaneously using resorbable mesoporous silicon. Claim 180 is indeed novel for the reasons already of record.

The Examiner's arguments fail to recognize that applicants are not claiming a resorbable

porous silicon sample. Indeed, applicants are claiming a method of administering a beneficial substance comprising the use of a resorbable mesoporous silicon sample and the method comprises subcutaneous implantation. With respect, it doesn't appear that the Examiner's comments fully take into account the difference between a product claim and a method claim.

By way of reminder, these issues were fully discussed in a communication dated August 16, 2007 (in connection with applicant's response dated July 10, 2007), where I explained these issues to the Examiner. However, given the lack of mention of subcutaneous implantation in the most recent Office Action, it seems reasonable to question if the Examiner is considering the current claim set.

Essentially, the present invention as currently claimed centers around the finding that mesoporous silicon can resorb following implantation in the subcutaneous layer. This would not have been obvious from the teaching of Canham (US or WO). There are a broad range of physiological environments in the body which provide very different environments and therefore different challenges in developing a sample of silicon which will be suitable for use in a particular environment.

For the above reasons it is respectfully submitted that all the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____


Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100